PRIVILEGED AND CONFIDENTIAL

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA
EX REL., HEIDI GREER AND MELISSA FUNK ,

PLAINTIFF/RELATOR,

v.

JOHNSON & JOHNSON D/B/A CENTOCOR,

DEFENDANT.

COMPLAINT
DEMAND FOR JURY TRIAL
CIVIL ACTION NO.
07 SC 11660 DWF/SRN

PLAINTIFF'S COMPLAINT UNDER 31 U.S.C. ' 3730 (UNDER SEAL)

PRIVILEGED AND CONFIDENTIAL

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA
EX REL., HEIDI GREER AND MELISSA FUNK ,

PLAINTIFF/RELATOR,

v.

JOHNSON & JOHNSON D/B/A CENTOCOR,

DEFENDANT.

CIVIL ACTION NO._____

MAGISTRATE:

FILED IN CAMERA AND UNDER SEAL

Relators Heidi Greer and Melissa Funk bring this complaint against the Defendant named above on behalf of the United States of America, its departments and agencies, including the Department of Health & Human Services ('DHHS"), as Plaintiff, showing the court as follows:

JURISDICTION AND VENUE

1. This is a case brought by the Relators against the Defendants under the Federal False Claims Act, 31 U.S.C. § 3729 et seq.

2. This court has jurisdiction of this action asserting claims arising under the laws of the United States pursuant to 28 U.S.C. § 1331.

3. This court has jurisdiction of this action in which the United States is a plaintiff pursuant to 28 U.S.C. § 1345.

4. This court has jurisdiction of the claims asserted in this action under the False Claims Act, 31 U.S.C. § 3729-33.

5. In accordance with 31 U.S.C. ' 3730 (b) (2), this complaint is filed in camera and will not be served on the Defendant until so ordered by the Court. A copy of the Complaint and

written disclosure of substantially all material evidence and information possessed by the Plaintiff have been served on the Government pursuant to 31 U.S.C. ' 3730 (b) (2) and Rule 4(i), Federal Rules of Civil Procedure.

6. Venue lies in this district under 31 U.S.C. § 3732(a) because the Defendant can be found in this district, the Defendant transacts business in this district, and one or more acts proscribed by 31 U.S.C. § 3729 occurred in this district.

7. Venue lies in this district under 28 U.S.C. § 1391(b) and (c) because the Defendant is a corporation that has one or more agents and places of business in this district and is subject to personal jurisdiction in this district, and a substantial part of the events giving rise to the claims asserted herein occurred in this district.

THE PLAINTIFF

8. The Plaintiff, the United States of America, by and through its department, DHHS, particularly the Center for Medicare & Medicaid Services ("CMS") within DHHS, is responsible for administering federal health programs, including Medicare and Medicaid.

9. The Medicare Program is a federally funded health insurance program that provides certain benefits for the elderly, the disabled, and those suffering from end-stage renal disease. Medicare was created in 1965 in Title XVIII of the Social Security Act. Medicare has two parts: Part A, the Basic Plan of Hospital Insurance, which covers the cost of hospital services and related ancillary services such as home health care agencies ("HHA's") and skilled nursing facilities ("SNF's"); and Part B, which covers the cost of physicians' services and other ancillary services not covered by Part A.

10. The Medicaid Program is a state and federal assistance program to provide payment of medical expenses for low income patients. The Medicaid program was also created

Federal Government and those states participating in the program: the funding apportionment varies from state to state but usually approximates an equal division. The primary purpose of the Medicaid program is to enable each state, as far as practicable under the circumstances in such state, to furnish medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services. States are required to provide certain basic services, such as in-patient hospital care to needy individuals. Medicaid covers approximately 47 million individuals, including children, the aged, blind, and/or disabled, and people are who eligible to receive federally assisted income maintenance payments. States may also cover prescription drugs under the Medicaid Program. 42 U.S.C. § 1396(d)(a)(12). Drugs reimbursed by Medicaid recipients account for roughly 10% of all prescription drugs purchased in the United States.

THE DEFENDANT

11. Defendant, Johnson & Johnson d/b/a Centocor, (hereinafter Centocor), is a foreign corporation that does business in the State of Minnesota and this district through its agents, employees, and subsidiaries.

12. Defendant Centocor sells its prescription medications, through intermediaries, to local hospitals, health care providers and other health care institutions/facilities, including *Infliximab*, under the brand name *Remicade*.

THE RELATORS

13. Relators Heidi Greer (Greer) and Melissa Funk (Funk), are citizens of the United States and the State of Minnesota, who reside in this district and division. Both Funk and Greer are former Centocor employees.

14. Funk began employment with Centocor in 1998. Greer began her employment with Defendant in May of 2000.

15. During Funk's employment with Centocor, Funk was employed as an Executive Immunology Specialist.

16. During Plaintiff Greer's employment with Centocor, Greer was employed as a Senior Area Business Specialist.

17. During the course of Greer and Funk's employment with Centocor, Centocor marketed and sold Remicade, an advanced biologic agent that is used to treat inflammatory disorders involving the immune system. As an Executive Immunology Specialist, it was Funk's job to sell Remicade. As a Senior Area Business Specialist it was Greer's job to, among other things, educate customers on Remicade reimbursement and educate customers on how to obtain access to Remicade through various sites of care.

CENTOCOR'S PRACTICES

18. As Centocor's sales force began marketing Remicade, Centocor began to incorporate marketing materials which described how physicians, hospitals, clinics and other providers could make money by prescribing Remicade. As part of this marketing effort, Centocor specifically described the revenue gains that could be made through Medicare coverage. Also as part of this marketing effort, Centocor began encouraging prescription of the drug for off-label use. During 1999-2000, Centocor was made aware that such practices violated or potentially violated the law yet continued the practices of selling for off-label use.

19. Centocor provided physicians with Medicare bulletins describing expanded indications to include off-label diagnoses including, but not limited to, treatment of Fetty's Syndrome, Juvenile Rheumatoid Arthritis and Psoriatic Arthritis.

20. Centocor utilized a Practice Management Program as a mechanism to present profit scenarios to practitioners based upon their practice's payor mix.

21. Centocor employed the use of Medicare Fee Managers who were responsible to provide training and guidance to practitioners for entitlement from Medicare based upon geographic adjustment rates.

22. As part of Centocor's Practice Optimization Procedures, the company encouraged physicians to round up doses of Remicade to full vials despite opportunities to split vials among scheduled patients or bill for the wasted portion of a vial. The effect of this guidance by Centocor was that it increased the cost of Remicade to the Medicare and Medicaid systems. The effect of this guidance on patients was an increased potential for risk of side effects from Remicade, including the increased potential for infections.

23. Centocor utilized its International Rheumatology Network management programs to educate physician members as to the profitability of optimizing the coding for Remicade in order to maximize practice profitability.

24. In or about 2002, Centocor publicly stated, in the New York Times, that all such unlawful marketing efforts had stopped in 2000. However, the unlawful marketing practices did not stop in 2000. Post 2000, Centocor, through its agents and employees, continued to market the profit potential of Remicade to its clients. Examples of the marketing materials include, but are not limited to, financial projections regarding in-patient infusions and Medicare reimbursements. In fact, one power point presentation to physician members of International Rheumatology Network contains an audible "Ka-Ching" sound (simulating a cash register) while a slide details the profit potential of Remicade.

27. Greer and Funk are personally familiar with Centocor's practices of soliciting physicians to prescribe Remicade because of the drugs profit potential as well as soliciting physicians for off-label use for the treatment of diseases and conditions not approved by the Federal Drug Administration ("FDA").

28. In addition to the foregoing, Relators observed during the course and scope of their employment that Centocor was using non-profit organizations to funnel money through an award of unrestricted grants in order to provide remuneration to physicians to prescribe its products. The supposed "grant" programs, supposedly used for purposes of research and education, were actually employed as a mechanism to obtain increased visibility for its products, including Remicade, and to encourage consideration of Remicade for off-label uses not approved by the FDA.

29. Centocor would work to set up and fund, through the use of "strawmen accounts", non-profit professional organizations in different states throughout the United States that were then used to create direct relationships with physicians through funding that would finance trips, seminars, meals and entertainment without limitation. As an example, Relators were encouraged to attempt to set up a non-profit in Minnesota called a state "society" of rheumatologists or gastroenterologists. Centocor would provide the initial funds by providing grants to the society after it was set up as reimbursement for start-up costs. Further, grants would be used to carry out the mission of the organization including lobbying for positive legislation to prevent potential reimbursement barriers for Remicade.

30. If non-profits could not be set up for some reason as a vehicle to provide remuneration to physicians, as an alternative, Centocor would provide honorariums to physicians

to present at seminars at rates above-market value, including seminars encouraging the use of Centocor products for off-label uses.

31. Centocor also engaged in a practice of using "preceptorships" as a mechanism to pay physicians for prescribing Centocor products. Centocor paid thousands, sometimes tens of thousands, of dollars through the use of "preceptorships" where Centocor employees would follow a physician that they wanted to prescribe its drugs around for a day under the premise of the Centocor employee "learning" about the physician's practice. The true reason for the unlimited "preceptorships" was to encourage the use of Centocor drugs and to suggest ways to use Centocor products for off-label use.

32. Centocor created a Contract Purchase Program in 2005, through which Centocor offered substantial discounts to its physicians and clinics that ordered and prescribed large quantities of Remicade. Centocor encouraged private clinics to exclusively be large volume purchasers – by encouraging off-label use, billing for whole rather than split vials and allowing private clinics to bundle their purchase codes (the number of orders under each code determined whether a provider would receive the large volume discount), while preventing hospitals and non-private clinics from doing the same. Centocor further encouraged these private clinics to be large volume purchasers by emphasizing the substantial profit they can make with each Remicade prescription, as described above. The effect of such practices was to drive up the average sale price (ASP) of the drug, the basis upon which Medicare and Medicaid's reimbursement cost is determined.

33. Greer and Funk are the original sources of relevant information upon which this action is based within the meaning of 31 U.S.C. § 3730(e)(4)(B).

34. Contemporaneously with the filing of this action, Relators have supplied information relevant to this action to the United States government. Subsequent to the filing of this action, Relators have continued to provide information relevant to this action to the United States government, as such information has become known to them.

THE MEDICAID REBATE OBLIGATION

35. In order to participate in the Medicaid Program and other government payment programs, pharmaceutical manufacturers are required by law to charge companies that sell, dispense, distribute, and administer their products the lowest price that other prudent and cost conscious buyers would incur for a given drug and submit quarterly rebate reports to the DHHS to ensure that the Federal Government is getting the best price for the products they supply. 42 U.S.C. § 1396r-8. *See PHRMA v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001).). 52 FR 28648.

36. The Medicaid Rebate Program was enacted as part of the Omnibus Budget Reconciliation Act of 1990, (hereafter OBRA) 1990, Pub.L.No. 101-508, § 4401, and is codified as amended in 42 U.S.C. § 1396r-8. That Code Section provides that "in order for payment to be available . . . for covered out-patient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement. . . with the Secretary [of HHS], on behalf of States..." 42 U.S.C. § 1396r-8(a)(1). The rebate obligation extends to all "covered outpatient drugs of the manufacturer . . . for which payment was made under the State plan." 42 U.S.C. 1396r-8(b)(l)(A).

37. Such pharmaceutical manufacturers are required by contract and law to make quarterly reports to the DHHS accurately disclosing the "best price" they offer covered pharmaceutical products for sale to anyone, and to rebate quarterly to the state Medicaid

agencies the price they charged Medicaid providers to the extent it exceeds the manufacturer's accurate "best price" for that quarter, so that the net price paid by Medicaid providers is the same as the "best price" the manufacturer offered anyone during that quarter.

38. The rebate due on each unit purchased under a State Medicaid Program is the difference between the average manufacturer price and the manufacturer's "best price", that is, the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States, or 15.1 percent of average manufacturer price, whichever is greater. 42 U.S.C. § 1396r-8(c)(l)(A),(B)and (C) and (C)(2). In other words, the rebate specified by 42 U.S.C. § 1396r-8 must reduce the price of the drug to a price that is either 15.1 % below the average price charged by the manufacturer for the drug, or the lowest price charged by the manufacturer for the drug to *any commercial customer* — whichever is less. *PHRMA v. Thompson*, 251 F.3d 219, 225 (D.C. Cir. 2001).

39. State Medicaid agency payments for brand name drugs such as Remicade must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of (1) the "Estimated Acquisition Cost"[1] plus reasonable dispensing fees or (2) Providers' usual and customary charges to the general public. 42 CFR § 447.331(b).

40. Medicaid programs are required to set the price as a cost conscious or prudent buyer of drugs. However to do so, they must rely on honest and accurate data from manufacturers such as Centocor.

41. Drug manufacturers must pay rebates to the States quarterly based on information provided by pharmacies regarding the number of units of prescription drugs purchased by

---

[1] "'Estimated acquisition cost' means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 CFR 447.301

Medicaid recipients and covered under the State plan. 42 U.S.C. § 1396r-8(b)(1-3), § 1396r-8(k)(8).

42. The state Medicaid agencies in turn credit the rebate payment against their claims for federal Medicaid reimbursement, so the "best price" rebates ultimately are for the use and benefit of the United States government.

THE FOOD, DRUG AND COSMETIC ACT REQUIREMENTS

43. The Food, Drug, and Cosmetic Act, as set forth in 21 U.S.C. § 301 *et seq.*, (FDCA) provides that unless exempted by the Food and Drug Administration (FDA) drugs can only be dispensed upon a written prescription of a licensed practitioner or upon an oral prescription of a practitioner and filled by an authorized pharmacist. Any act of dispensing a prescription drug without a lawful prescription contrary to the provisions of the FDCA "shall be deemed to be an act which results in the drug being misbranded while held for sale." 21 U.S.C. § 353(b)(1).

44. "Misbranding" is a criminal act, punishable under 21 U.S.C. §§ 331 and 333. Misbranding done with intent to mislead or defraud is a felony, punishable by up to three years imprisonment and a fine of up to $10,000 per violation. 21 U.S.C. § 333(a)(2).

45. Under the FDCA, 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. *See* 21 U.S.C. § 355(a) and (d).

46. Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such "off label" usage is an accepted corollary of the

FDA's mission to regulate pharmaceuticals without directly interfering with the practice of medicine.

47. Although physicians may prescribe drugs for off-label usage, the FDA prohibits drug manufacturers and distributors from marketing or promoting a drug for a use that the FDA has not approved. *See* 21 U.S.C. § 331(a) (prohibiting distribution of a "misbranded" drug); 21 U.S.C. § 331(b) and (k) (prohibiting misbranding of drugs); 21 U.S.C. § 331(d) (prohibiting distribution of drugs for non-approved uses), 21 U.S.C. §§ 331(z), 36Oaaa and 36Oaaa-1 (prohibiting dissemination of information about a drug that is false or misleading and would pose a significant risk to the public health.).

48. A distributor or manufacturer illegally "misbrands" a drug if the drug's labeling includes information about its unapproved uses.

49. If the distributor or manufacturer intends to promote the drug for new uses in addition to those already approved, the materials on off-label uses must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process. 21 U.S.C. § 334 (setting forth the requirements in the Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 36Oaaa, *et seq.*)

50. Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10).

51. Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A medically accepted indication includes a use "which is approved under the Federal Food Drug

and Cosmetic Act" or which is included in specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). See also 42 U.S.C. § 1396r-8(g)(l)(B)(i) (identifying compendia to be consulted: American Hospital Formulary Service Drug Information; United States Pharmacopeia-Drug Information; the DRUGDEX Information System; and American Medical Association Drug Evaluations).

52. Unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

53. Examples of off-label promotion by Centocor include, but are not limited to:

a. During the course of Greer and Funk's employment with Centocor, Centocor sales personnel were directed to research and "write up" every off-label use of Remicade of which they were aware and solicit doctors to write up off-label uses for which they were using Remicade. This information was written up as abstracts and submitted for presentation at national meetings for organizations such as; the American College of Rheumatology, DDW, ACG, AAD, etc.

b. Centocor sales personnel were informed via confidential interoffice memo whenever Medicare or a health plan started reimbursing for Remicade for off-label uses. As an example, a Centocor interoffice memorandum alerted the sales force that United Health Care was covering Remicade for Psoriatic Arthritis and that the sales force's plan of action was to "communicate to provider's new coverage for maintenance and PSA" and further noting "United is helping to set the standard of care for patients with Crohn's disease by covering maintenance therapy even before we [Centocor] have the indication"

c. Centocor set up physician and patient education programs in which the subject matter discussed was off-label uses for Remicade as an attempt to encourage sales representatives to market the drug to physicians and patients for the off-label uses.

d. Centocor provided training to its sales personnel regarding off- label uses for Remicade and further provided its sales personnel with literature to distribute to physicians regarding the off-label uses for Remicade.

e. Centocor maintained a practice of permitting its sales force to request off-label use information be sent to physicians without validating or otherwise authenticating the physician's medical inquiry. As a result, Centocor sales personnel requested, without physician inquiry, off-label information be provided to physicians.

f. Centocor provided its sales force with talking points that could be used to discuss off label uses for Remicade. For example, a "Centocor educational" FAQ provided sales representatives with instructions to give the following response to a question regarding whether Remicade is reimbursable for Ankylosing Spondylitis: "As you know the FDA has not approved any anti-TNF therapy for the treatment of Ankylosing Spondylitis, so policies can vary by payor. Because there are not real treatment options for patients with this disease, some payors may be willing to review this on a case-by-case basis. Would you like additional information from our Medical Information department?" The sales staff was also made aware of who was covering or had covered Remicade for such a use.

g. Centocor hired an entire off-label sales force to sell the drug Retavase to interventional radiologists for peripheral catheter clearance even though Retavase did not have the indication.

THE SCHEME TO DEFRAUD THE GOVERNMENT

54. Defendant Centocor devised and executed a scheme to defraud the United States government by evading payment to the Government of tens, if not hundreds, of millions of dollars of rebates due and reimbursements made for prescriptions relating to Remicade to Medicaid and Medicare providers by manipulating the drug's ASP, and therefore setting the federal program's "best price," and for soliciting the use of Remicade for off-label use for non-approved treatment modalities, as well as marketing the profitability of Remicade to physicians.

55. Upon information and belief, Centocor entered into a participation agreement with the United States government where Centocor agreed that the Medicaid and Medicare programs would receive the best price for any of its pharmaceutical products, including Remicade, that it charged to any commercial purchaser for those products, taking into account discounts, rebates, promotional incentives, and any other financial inducements offered to

commercial purchasers to promote the purchase, distribution, dispensation, and use of Centocor's products.

56. *Beginning in early 2005* Defendant Centocor devised and implemented a promotional pricing scheme and practice for selling and distributing Remicade to physicians and other health providers – the Centocor Contract Purchase Program. Under this program, private practitioners and clinics were offered discounts on large volume orders, thus increasing the average sale price (ASP). These same pricing discounts were not extended to hospitals, health systems or home infusion orders. Therefore, the Medicaid and Medicare programs were charged significantly more for the same drug as compared to Centocor's preferential, high prescribing customers.

57. Defendant Centocor knew, intended, or reasonably should have known and foreseen, that providers would promote the use of Remicade instead of competing drugs to increase their profit margin by taking advantage of promotional discounts, incentives and any other financial inducements Centocor offered to reduce their cost of purchasing Remicade, while at the same time charging hospitals and health systems a higher price.

58. Defendant Centocor knew, intended, or reasonably should have known and foreseen, that its pricing scheme and practice would maintain physician profits and cause large numbers of patients who needed this type of drug to be prescribed Remicade, rather than other competitor drugs, by physicians, hospitals, clinics and other health care facilities given the financial incentives promised by Centocor. Some physicians were realizing an excess of one million dollars of profit based wholly on their annual prescriptions of Remicade.

59. This pricing scheme and practice is a marketing strategy Centocor knowingly and deliberately intended to result in unnecessarily high prices for Remicade charged to Medicaid,

Medicare and other federal programs, as well as private pay patients and those with private insurance benefits as compared to the prices the drug was sold for to preferred customers.

60. Defendant Centocor knew, intended, or reasonably should have known and foreseen, that this pricing scheme and practice would induce providers to engage in unauthorized medication substitution, a practice euphemistically called "therapeutic interchange" or "therapeutic substitution". By this practice, providers supplant and replace their independent medical judgment based upon financial incentives offered by the drug manufacturer or through the solicitation of the drug manufacturer's representative for off-label drug use. To accomplish such a substitution, Centocor used financial inducements to physicians, showing them how they could make a profit prescribing Remicade and how the drug could be used for the treatment of many other diseases or conditions that the company did not have indications for from the FDA.

61. Centocor knew or should have known that Remicade was not chemically or therapeutically identical or interchangeable with other competing drugs.

62. The schemes and practices alleged are nationwide in scope as the Relators observed that the identical training and directives were provided to all employees holding similar positions throughout the United States.

63. Beginning the first quarter of 1991 through the present date, Centocor was required to report quarterly its best price and pay rebates to the state Medicaid programs so that the program received comparable discounts.

64. Defendant Centocor knowingly, willfully, wantonly, recklessly, and unlawfully knowingly makes, uses, or caused to be made or used, a false and inaccurate rebate report to conceal, avoid, or decrease its obligation to pay money or property to the government in violation of 31 U.S.C. § 3729 (a)(4) and (7).

65. Because neither the true "best price," nor the data from which it can be determined, was ever accurately reported to the DHHS and CMS, the United States government is caused a financial loss, and Defendant Centocor reaps a financial windfall at the government's expense by receiving inflated prices for Remicade from the Medicaid and Medicare programs.

66. Centocor has therefore knowingly, willfully, wantonly, and recklessly submitted false statements, and reports to the Government which are in violation of the False Claims Act, and for which Centocor should be held legally liable in damages, penalties, and litigation costs and expenses.

CENTOCOR'S VIOLATION OF OIG COMPLIANCE

67. Because the increasing number of pharmaceutical manufacturers, including Centocor, that have knowingly, willfully, and repeatedly failed to provide accurate prescription drug pricing data, the Office of the Inspector General of the DHHS issued a warning to manufacturers regarding the penalty for failing to provide accurate pricing data to Medicaid and Medicare programs.

68. In April of 2003, OIG and the Department of Justice published Model Compliance for Pharmaceutical Manufacturers at 68 FR 23731. This guidance was to reiterate existing laws and policies to ensure that manufacturers continue to maintain the integrity of the data they provide to government payment programs such as Medicaid, etc.

69. Specifically, OIG and DOJ warned manufacturers with the following language:

> Integrity of Data Used To Establish or Determine Government Reimbursement. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare

and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti- kickback statute.

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B Program), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs.

In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.

70. In this warning, the government reiterated that without honest and accurate data such as "best price" from manufacturers, the purposes of the program would be impeded.

71. Defendant Centocor's actions regarding its pricing scheme and practices for Remicade are clearly in violation of the explicit warnings of OIG and DOJ in this guidance document.

CENTOCOR USES ALTER EGO NON-PROFITS TO SUBVERT THE ANTI-KICKBACK PROVISIONS OF THE STARK REGUALTIONS

72. In addition, Relators observed during the course and scope of their employment that that Centocor was using non-profit organizations to funnel money through an award of grants in order to provide inducements to physicians and pharmacists to prescribe its products.

The supposed "grant" programs used by Centocor are merely schemes to get around the anti-kickback provisions of the Stark legislation.

73. Centocor provided unrestricted grants of tens of thousands of dollars to non-profits which would be used directly to provide for start up costs and to sponsor supposed "educational" events and seminars that were truly intended for entertainment purposes including golf tournaments, fishing trips, receptions as well as weekend retreats to providers. The education at the events concerned the profitability of Remicade and its potential off-label use. As an example, Centocor provided funding to the "International Rheumatology Network" to start up the non-profit in Minnesota with the expectation of these "educational" events when, in fact, funds would be spent wining and dining physicians to encourage the physician participants to prescribe Centocor's products.

74. Centocor specifically created a "Field Advocacy" team to help rheumatology societies across the country secure and protect Remicade reimbursement procedures.

75. Pursuant to Centocor's own policy, employees were not allowed to participate in the "entertainment" functions as the same might violate Stark anti-kickback regulations. Nonetheless, it was a regular occurrence for Centocor managers and sales representatives to participated in programs and entertainment provided by the funded organizations.

76. Centocor used non-profits as alter egos for itself in order to obtain access to physicians and as a mechanism to get around the Stark anti-kickback regulations that govern pharmaceutical companies.

77. The ruse, as observed by Relators, gave Centocor a significant competitive advantage over other pharmaceutical companies and such practices clearly violated the federal anti-kickback provisions.

78. Centocor also routinely paid physicians who prescribed large volumes of its drugs "honorariums" to give speeches where there existed no educational purpose and where there was no relationship between the fees paid the physician and the amount of time necessary to conduct the speech. Further, Centocor used "preceptorships" as a means to compensate physicians to allow Centocor employees to follow them around for a day. The preceptorships were merely an avenue for Centocor to provide remuneration to physicians in order to get around anti-kickback regulations and a method of encouraging physicians to use Centocor products for both indicated purposes and off-label purposes.

79. Relators is the original source of relevant information upon which this action is based within the meaning of 31 U.S.C. § 3730(e)(4)(B).

80. Contemporaneously with the filing of this action, Relators have supplied information relevant to this action to the United States government. Subsequent to the filing of this action, Relators have continued to provide information relevant to this action to the United States government, as such information has become known to him.

81. As a result of the illegal inducements and kickbacks, Centocor has knowingly, willfully, wantonly, and recklessly submitted, either directly or indirectly, false statements, and reports to the Government which are in violation of the False Claims Act, and for which Centocor should be held legally liable in damages, penalties, and litigation costs and expenses.

COUNT I
VIOLATIONS OF FALSE CLAIMS ACT

82. Despite compliance requirements imposed upon Defendant Centocor over and above that of other manufacturers as a result of Centocor's prior illegal conduct, and in the face of repeated warnings of government agencies, Centocor has continued to fail to report accurate pricing data to Medicaid and Medicare of its "best price"

83. Continuing through the date of filing of this Complaint, Centocor, through its agents, employees, and subsidiaries, did unlawfully and knowingly devise and carry out a scheme to defraud the federal government in general, and the Medicare and Medicaid Programs and other federal health programs in particular, and to impair, impede, obstruct, and defeat the lawful governmental functions of these programs.

84. In furtherance of this scheme to defraud and submit false and fraudulent claims to the United States, Centocor charged inflated prices for Remicade to providers participating in Medicaid, Medicare, and other federal heath care programs, when Remicade was sold to other providers at vastly reduced prices.

85. Centocor knowingly and willfully created this pricing scheme and practice in order to garner large profits for its Remicade drug.

86. Through the use of this pricing scheme and practices, Centocor knowingly, willfully, and unlawfully induced medical providers to substitute its drug Remicade for competitive drugs specifically prescribed by patients' physicians without patient specific prior physician authorization often in violation of State Medical, Pharmacy, and Nursing practice acts, and the Food, Drug, and Cosmetic Act. 21 USC § 301, *et seq*.

87. Centocor did knowingly, willfully, and unlawfully cause to be charged participating providers in the Medicaid, Medicare, and other government programs excessive and inflated prices for Remicade.

88. Centocor did knowingly, willfully, and unlawfully cause Medicaid, Medicare and other government programs to be charged excessive and inflated prices for Remicade.

89. Centocor knowingly and willfully failed to report, or report accurately, the sales of Remicade to preferred prescribers at discounts, rebates, promotional incentives, and any other

financial inducements alleged in this complaint to CMS on a quarterly basis, which would have required Centocor to pay substantially higher rebates to the state Medicaid agencies.

90. Centocor did knowingly, willfully, and unlawfully file false reports and claims to governmental agencies for the computation of prices by rebate programs administered by the Federal Government and States, including but not limited to best price, average sale price, and average manufacturers price certifications, including but not limited to those requirements set forth in 42 U.S.C. § 1396r-8.

91. Centocor did knowingly, willfully, and unlawfully control the published data and manipulated those prices to maximize its government reimbursement and to avoid its obligation to pay rebates to government agencies.

92. Centocor did knowingly, willfully, and unlawfully use its position as a reporter of pricing data to prevent, hinder, interfere with, and obstruct government health programs from receiving the intended benefit of the lowest prices for Remicade as mandated by Congress in its enactment of those relevant statutes.

93. Centocor did knowingly, willfully, and unlawfully cause false statements to be made and used by others in order to have false and fraudulent claims paid by the Medicaid, Medicare, and other government programs. Such bills or statements of claims were made for unauthorized dispensation of Remicade supplied to the billing provider. These orders either were often prescribed as the result of an illegal inducement by which Defendant Centocor usurped or supplanted the independent medical judgment of physicians.

94. Centocor did knowingly, willfully, and unlawfully induce medical providers through pricing discounts to switch patients to Remicade from less expensive drugs. Such inducement was not merely a price discount, but was remuneration to the medical providers in

order to purchase Remicade for use in patients covered by various federal and state health programs. Such financial inducements were given in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

95. Centocor's Remicade pricing scheme and practices resulted in known, intended, or reasonably foreseeable drug substitutions designed to gain market share and to circumvent the clinical decision-making of physicians and licensed practitioners, pharmacists, and nurses.

96. Centocor's pricing scheme and practices promote misbranding of drugs prohibited by the Food, Drug and Cosmetic Act, 21 USC § 301, *et seq*. and caused medical providers to violate state medical practice, pharmacy practice, and nursing practice Acts, as well as well as the Model Practice Act of the Federation of State Medical Boards, which many states have adopted in substantial part. Dispensing medication under these circumstances violates the Medicaid/Medicare conditions of participation. Any bills submitted as a result of this practice of substitution are false claims, and Centocor has caused to false claims to be filed with and made against the government as a result thereof.

97. By such acts and omissions, Centocor has caused a monetary loss to the United States of America, through the Medicare and Medicaid programs, as well as other government health programs, and direct payment systems. The amount of which loss is the aggregate of the amounts expended on the following items, among others, (1) the cost differential between the prices charged to Medicare and Medicaid for Remicade, and the prices charged to preferred customers; (2) any and all reimbursements for off-label use of Remicade; and (3) any and all reimbursement for all sales realized as a result of illegal remuneration to physicians including, but not limited to, sales resulting from the illegal use of non-profits as alter egos, sales resulting

from above-market honorariums, and sales resulting from preceptorships. Each scheme and practice constitute violations of 31 U.S.C. § 3729 *et seq*.

COUNT II
FALSE CLAIMS ACT RETALIATION

Plaintiffs/Relators incorporate paragraphs 1 through 97 herein.

98. Plaintiffs/Relators Greer and Funk, in good faith, reported what they believed to be violations of state and federal laws including, but not limited to Section 3729 *et seq* of the False Claims Act which prohibits the use of fraud or misrepresentation to obtain monetary benefits from the United States Government.

99. Defendants have engaged in illegal conduct perpetrated against the most vulnerable people in society-- senior citizens, the poor and handicapped persons.

100. Defendants' illegal acts have caused senior citizens, the poor, and handicapped persons to be denied basic rights to care and have caused injury to the taxpayers of the United States. This conduct of Defendants violates public policy against theft and fraud perpetrated upon the vulnerable and upon the United States of America.

101. Plaintiffs/Relators Greer and Funk were retaliated against by Defendants as a result of their reports including, but not limited to, denial of employment opportunities and termination.

102. The adverse employment actions as alleged herein constitute violations of 31 U.S.C. § 3730(h).

103. As a direct and proximate result of Defendants' conduct, Plaintiffs/Relators have suffered, and continue to suffer emotional distress, humiliation, embarrassment, pain and suffering, loss of reputation, loss of wages, benefits and reimbursable out-of-pocket expenses, attorneys' fees, costs and other serious damages.

WHEREFORE, the Relators Heidi Greer and Melissa Funk pray for judgment in favor of the Plaintiff United States and the Relators, and against Defendant Centocor as follows:

(a) That Centocor cease and desist from violating 31 U.S.C. § 3729 *et seq.*;

(b) That the Court enter judgment in favor of the Plaintiff United States and the Relators Greer and Funk against Centocor in an amount equal to three times the amount of damages the United States has sustained as a result of Cenotocor's actions and omissions, plus interest, as well as a civil penalty against each Defendant of $10,000 for each violation of 31 U.S.C. § 3729;

(c) That the Plaintiff United States and Relators Greer and Funk be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the Federal False Claims Act;

(d) That the Plaintiff United States and the Relators Greer and Funk be awarded all costs and expenses of this action, including attorneys' fees;

(e) That Plaintiffs/Relators Greer and Funk be awarded compensatory damages to make them whole, including damages for emotional distress, past and future, as well as wages, benefits and reimbursable out-of-pocket expenses, past and future, plus interest and attorneys' fees, costs, and such further relief as may be just and proper as a result of their retaliatory discharges; and

(f) That the Plaintiff United States and Relators Greer and Funk receive all such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Dated this 22nd day of March, 2007.

HALUNEN & ASSOCIATES

Clayton D. Halunen- 219721
Christopher D. Jozwiak- 0386797
220 South Sixth Street
Suite 2000
Minneapolis, Minnesota 55402
(612) 605-4098

NEATON & PUKLICH
Michael L. Puklich- 0250611
601 Carlson Parkway
Suite 620
Minnetonka, MN 55305
(952)258-8444

#16507

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

07-1660 DWF/SRN

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

UNITED STATES OF AMERICA EX REL. HEIDI GREER AND MELISSA FUNK

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

Complaint filed Under Seal

(c) Attorney's (Firm Name, Address, and Telephone Number) Clayton Halunen, HALUNEN & ASSOCIATES, 220 S. 6th St, Suite 2000, Minneapolis, MN 55402

DEFENDANTS

JOHNSON & JOHNSON D/B/A CENTOCOR

County of Residence of First Listed Defendant Unknown
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- [X] 1 U.S. Government Plaintiff
- [ ] 3 Federal Question (U.S. Government Not a Party)
- [ ] 2 U.S. Government Defendant
- [ ] 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	[ ] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[ ] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
[ ] 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	[ ] 610 Agriculture	[ ] 422 Appeal 28 USC 158	[ ] 400 State Reapportionment
[ ] 120 Marine	[ ] 310 Airplane	[ ] 362 Personal Injury - Med. Malpractice	[ ] 620 Other Food & Drug	[ ] 423 Withdrawal 28 USC 157	[ ] 410 Antitrust
[ ] 130 Miller Act	[ ] 315 Airplane Product Liability	[ ] 365 Personal Injury - Product Liability	[ ] 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	[ ] 430 Banks and Banking
[ ] 140 Negotiable Instrument	[ ] 320 Assault, Libel & Slander	[ ] 368 Asbestos Personal Injury Product Liability	[ ] 630 Liquor Laws	[ ] 820 Copyrights	[ ] 450 Commerce
[ ] 150 Recovery of Overpayment & Enforcement of Judgment	[ ] 330 Federal Employers' Liability	PERSONAL PROPERTY	[ ] 640 R.R. & Truck	[ ] 830 Patent	[ ] 460 Deportation
[ ] 151 Medicare Act	[ ] 340 Marine	[X] 370 Other Fraud	[ ] 650 Airline Regs.	[ ] 840 Trademark	[ ] 470 Racketeer Influenced and Corrupt Organizations
[ ] 152 Recovery of Defaulted Student Loans (Excl. Veterans)	[ ] 345 Marine Product Liability	[ ] 371 Truth in Lending	[ ] 660 Occupational Safety/Health		[ ] 480 Consumer Credit
[ ] 153 Recovery of Overpayment of Veteran's Benefits	[ ] 350 Motor Vehicle	[ ] 380 Other Personal Property Damage	[ ] 690 Other		[ ] 490 Cable/Sat TV
[ ] 160 Stockholders' Suits	[ ] 355 Motor Vehicle Product Liability	[ ] 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	[ ] 810 Selective Service
[ ] 190 Other Contract	[ ] 360 Other Personal Injury		[ ] 710 Fair Labor Standards Act	[ ] 861 HIA (1395ff)	[ ] 850 Securities/Commodities/ Exchange
[ ] 195 Contract Product Liability			[ ] 720 Labor/Mgmt. Relations	[ ] 862 Black Lung (923)	[ ] 875 Customer Challenge 12 USC 3410
[ ] 196 Franchise			[ ] 730 Labor/Mgmt.Reporting & Disclosure Act	[ ] 863 DIWC/DIWW (405(g))	[X] 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	[ ] 740 Railway Labor Act	[ ] 864 SSID Title XVI	[ ] 891 Agricultural Acts
[ ] 210 Land Condemnation	[ ] 441 Voting	[ ] 510 Motions to Vacate Sentence	[ ] 790 Other Labor Litigation	[ ] 865 RSI (405(g))	[ ] 892 Economic Stabilization Act
[ ] 220 Foreclosure	[ ] 442 Employment	Habeas Corpus:	[ ] 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	[ ] 893 Environmental Matters
[ ] 230 Rent Lease & Ejectment	[ ] 443 Housing/ Accommodations	[ ] 530 General		[ ] 870 Taxes (U.S. Plaintiff or Defendant)	[ ] 894 Energy Allocation Act
[ ] 240 Torts to Land	[ ] 444 Welfare	[ ] 535 Death Penalty		[ ] 871 IRS—Third Party 26 USC 7609	[ ] 895 Freedom of Information Act
[ ] 245 Tort Product Liability	[ ] 445 Amer. w/Disabilities - Employment	[ ] 540 Mandamus & Other			[ ] 900Appeal of Fee Determinatio Under Equal Access to Justice
[ ] 290 All Other Real Property	[ ] 446 Amer. w/Disabilities - Other	[ ] 550 Civil Rights			[ ] 950 Constitutionality of State Statutes
	[ ] 440 Other Civil Rights	[ ] 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

[X] 1 Original Proceeding [ ] 2 Removed from State Court [ ] 3 Remanded from Appellate Court [ ] 4 Reinstated or Reopened [ ] 5 Transferred from another district (specify) [ ] 6 Multidistrict Litigation [ ] 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
31 U.S.C. Sec. 3730

Brief description of cause:
Claim under the False Claims Act

VII. REQUESTED IN COMPLAINT:

[ ] CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $ $300,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: [X] Yes [ ] No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 3/26/2007

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____